UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS;	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	)	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	)	

VEN-A-CARE OF THE FLORIDA KEYS, INC.'S COMBINED OPPOSITION TO MOTIONS TO DISMISS FILED BY ABBOTT, DEY AND ROXANE

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The Relator, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care" or "VAC"), files this combined response to the Defendants' Motions to Dismiss[1] pursuant to Federal Rule of Civil Procedure 12(b)(1) wherein they allege that this Court lacks subject-matter jurisdiction under the False Claims Act's Public Disclosure Bar set forth at 31 U.S.C. § 3730(e)(4).

I. INTRODUCTION

Ven-A-Care's service as *a qui tam* relator is unprecedented in the 146 year history of the False Claims Act. It began in 1991 when its principals were invited to participate in a physician referral kickback arrangement funded by inflated reimbursement on pharmaceutical products. [Exh. D to the Declaration of Susan Schneider Thomas (hereafter, "Ex. ___," unless otherwise stated, refers to exhibits to the Thomas Declaration), Jones Tr., May 9, 2007, at 81:10-89:6]. The deal, sponsored by one of the largest healthcare companies in the world, National Medical Care and its parent WR Grace Corporation, was premised on the exploitation of terminally ill patients by inducing healthcare providers to look at profits, rather than patients' medical needs alone.[2] *Id.* Rather than join the venture, Ven-A-Care accepted the ruin of its lucrative pharmacy business and immediately reported its information to the Department of Justice and the most influential member of Congress it could think of in the health care arena, Pete Stark of the House Ways and Means Committee. *Id*. at 71:24-74:13; [Exh. E, Jones Tr., Dec. 8, 2008, at 750:10-751:22; Exh. F, Lockwood Tr., July 27, 2009 at 60:5-12].

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[1] This Court has granted leave for Ven-A-Care to file a combined response to the Defendants' motions. October 15, 2009 Order on Consent Motion to Modify Briefing Schedule and Consolidate Opposition to Defendants' Motions to Dismiss Into One Memorandum of Law; Docket No. 6583-2.

[2] Ven-A-Care was invited into a physician referral venture that tainted physician judgment in the care of AIDS patients and discovered similar kick-back arrangements exploiting dialysis patients suffering from End Stage Renal Disease (ESRD) whose care was paid for by Medicare and Medicaid.

Congressman Stark used the information supplied by Ven-A-Care to assist him in securing the passage of the "Stark II" laws prohibiting certain kinds of physician referral arrangements. [Exh. G, Jones Tr., Dec. 9, 2008 at 1294:9-1298:3]. Congressman Stark also asked Ven-A-Care to provide information to the HHS Office of Inspector General on pharmaceutical reimbursement and marketing issues, and Ven-A-Care has done so for more than 18 years. [Exh. F at 60:5-12; *see also* Exh. C, T. Mark Jones Declaration, at Exh. 2]. Ven-A-Care's assistance began with infusion and injectable pharmaceutical products, including those distributed by Abbott and at issue in this case. [Exh. H, Jones Tr., Mar. 18, 2008, at 285:12-289:1; Exh. C, Exh. 2 at VAC MDL 81168-81173; Exh. C, Exh. 2 at VAC MDL 74253-74257; *see also* communications referenced in Exh. C, Exh. 2].

Contrary to defendants' insinuations and accusations that Ven-A-Care merely pirated public information, from the very beginning, the OIG, Congress, the Justice Department and various states have used Ven-A-Care's information about confidential insider pharmaceutical transaction prices and marketing practices. This has been especially important because Ven-A-Care is in business in an industry whose participants closely guard their transaction prices and practices. Ven-A-Care observed those pricing and marketing practices over time from the vantage point of an industry insider to whom the inducements are arranged and directed. As will be discussed below, Ven-A-Care was the government's ongoing source of such information including about Abbott's infusion and injectable drugs beginning in 1994[3], Dey's nebulizer and

[3] *See*, e.g., Exh. C, Exh. 2 at VAC MDL 74262-74294, VAC MDL 74185-74252, VAC MDL 81208-81218.

inhalant drugs beginning in 1995[4] and Roxane's ipratropium bromide and other drugs beginning in 1996[5].

While Ven-A-Care has been voluntarily and aggressively assisting the government to understand and respond to pharmaceutical-related fraud since 1991[6], it did not commence its first FCA *qui tam* case until 1994, after being encouraged to do so by an HHS OIG official.[7] Ven-A-Care's *qui tam* cases have, to date, returned more than a billion dollars to the federal and state treasuries,[8] yet the defendants describe Ven-A-Care as a "parasite" whose efforts should be eviscerated. Since the word the defense asks this Court to apply appears nowhere in the FCA, the dictionary definition is instructive, and alone exposes the complete lack of merit of the defense's primary contention:

> par•a•site (par-′ə-sīt′) *n*. 1. ***Biol.*** An organism that grows, feeds, and lives on or in another organism to whose survival it contributes nothing. 2.a. One who habitually takes advantage of generosity without making any useful return.

The American Heritage College Dictionary, 3rd ed. (Houghton Mifflin Co., Boston, 1993)

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[4] *See*, e.g., Exh. C, Exh. 2 at VAC MDL 48643-48645, VAC MDL 49888, VAC MDL 49845-49848, and VAC MDL 43646-43650.

[5] *See*, e.g., Exh. C, Exh. 2 and VAC MDL 49771-49775.

[6] Since 1990 if one considers assistance provided to Florida Medicaid with respect to the cost of Total Parenteral Nutrition. [Exh. D at 81:10-89:6; 71:24-74:13; Exh. E at 750:10-751:22; Exh. F at 60:5-12]

[7] *See* Exh. C at ¶25.

[8] Ven-A-Care and its counsel team sought and received permission from the United States District Court for the Southern District of Florida in 1997 to inform the states' attorneys general about the pharmaceutical pricing fraud, to bring state *qui tam* actions and to otherwise assist the states. As the Court is aware, Ven-A-Care has helped to fund and staff numerous related state *qui tam* actions and has assisted non-*qui tam* states with investigations and civil actions. [Exh. C at ¶¶27-29].

The defense choice of the word "parasite" to describe Ven-A-Care's efforts is extremely ironic. In 1992, as Ven-A-Care began its efforts to expose the fraud relating to infusion and injectable drugs, which Abbott had already embarked upon, Dey Laboratories initiated a marketing scheme designed to create and exploit the spread on Medicare and Medicaid reimbursement;[9] in 1995, while Dey intentionally inflated its wholesaler acquisition cost (WAC) reports in order to exploit Medicaid reimbursement in WAC states and marketed an inflated spread that would corrupt the DME marketplace, Ven-A-Care filed its first AWP related *qui tam* action and informed the government about the nebulizer drug scheme;[10] in 1996, as Ven-A-Care assisted the OIG by providing it with the transaction prices it would use for its 1997 reports on Medicaid reimbursement, Roxane devised a scheme to create and market inflated spreads on ipratropium bromide;[11] in 2000 as Ven-A-Care educated the Department of Justice about the role of ipratropium bromide in Roxane's fraud scheme, Roxane's senior executives, believing that the government's investigation of other companies focused on regular generics, planned to expand the scheme to Roxane's branded generics.[12] It was Ven-A-Care's information and allegations that led to, and indeed made possible, the government investigations and civil fraud prosecution of each of the defendants who now call Ven-A-Care a "parasite" for blowing the whistle on their fraudulent exploitation of scarce Medicare and Medicaid dollars to fund their marketing inducements. If there is a parasite here, it is not Ven-A-Care.

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[9] *See* Exh. I.

[10] *See* Exh. 2 of Exh. C, at VAC MDL 48643-48645, VAC MDL 49888, VAC MDL 49845-49848, and VAC MDL 43646-43650, and Exh.OO at DL-TX-0122497.

[11] *See* Exh. J at p. ROX 04610 (launch plan noting a "price structure" was selected to "create an attractive spread").

[12] *See* Exh. K.

The Defendants' assertion that this Court lacks subject-matter jurisdiction is contrary to this Court's recent order denying the motions to dismiss in *United States ex rel. Ven-A-Care v. Actavis, et al.*, and is also defeated by the defendants' own statements of fact in the summary judgment filings in these cases. The Defendants here rely on the same kinds of government reports (indeed, some of the same reports) that this Court rejected as public disclosures in *Actavis*. Moreover, the Defendants in the present case also assert, in their recent Rule 56 Statements of Undisputed Facts, that Ven-A-Care's disclosures and allegations *put the government on notice* of their fraud scheme.[13]

Despite their "kitchen sink" identification of 200 odd documents as purported public disclosures, Defendants have failed to point to *any* public disclosure of allegations or transactions, as defined by 31 U.S.C. § 3730(e)(4)(A), occurring prior to VAC's initiation of the actions and upon which the actions are based. Moreover, even if the public disclosure bar were to apply, Ven-A-Care is an original source because it has direct and independent knowledge of the information upon which its allegations are based and provided that information to the government before filing its actions. 31 U.S.C. § 3730(e)(4)(B). Accordingly, this Court possesses subject-matter jurisdiction over the Relator's actions.

II. FACTUAL BACKGROUND

Ven-A-Care, a Florida corporation, was formed as a small closed, specialty pharmacy in 1987 by Luis Cobo and T. Mark Jones in Key West, Florida for the purpose of providing infusion, inhalation, injectable and other drugs to seriously ill patients in their homes and in other

[13] *See, e.g.*, Roxane SOF 37-49 filed on 06/29/2009, Dkt. Nos. 6199 and 261, and Dey's Declaration of Sarah Reid, Dkt. Nos. 6206 and 266, filed on 6/26/2009, Exhibits 65-97. Of course Ven-A-Care disagrees with the defense conclusion that a relator who notifies the government of a fraud scheme somehow immunizes defendants from FCA liability for future acts.

locations outside the hospital setting. [Exh. L, Cobo Tr., Mar. 3, 2003, at 13:10-13:16; Exh. H at 101:1-102:2]. Ven-A-Care obtained a community or retail pharmacy license in 1991 and, thereafter, provided oral and other types of drugs normally dispensed by a retail pharmacy. [Exh. C at ¶3].

Ven-A-Care's business did well until August 1991 when it was invited to join the W.R. Grace/NMC-led physician joint venture. [Exh. D, at 81:10-89:6].[14] Ven-A-Care saw the inflated reimbursements in the NMC case as corrupting the healthcare marketplace and a barrier to its ability to lawfully compete. [Exh. N at 81:10-89:6]. VAC met this challenge by investigating what it perceived to be reimbursement-related fraud and conducted a comprehensive study of the effect on Medicare and Medicaid throughout the United States. [Exh. O, Bentley Tr., Mar. 6, 2008, at 541:9-542:22; *e.g.*, Exh. P, VACMDL 73407]. In December of 1994, Ven-A-Care sent a letter to Alicia Valle, Assistant United States Attorney, Southern District of Florida, alerting the Government to the false prices occurring in the marketplace and the resulting inflated reimbursements. *See* Exh. C, Exh. 2. Thereafter, VAC continued its ongoing discussions with the HHS/OIG, and met with Ms. Valle and Mr. Lavine of the Miami United States' Attorney's Office to provide a detailed explanation of the fraud occurring in the pharmaceutical marketplace, including references to specific companies' drugs and prices. [Exh. C, Exh. 2].

Initially VAC's information centered on the infusion and injectable drug products, such as those distributed by Defendant Abbott. In August of 1995, however, Ven-A-Care was again presented with an opportunity to enrich itself through inflated reimbursement, this time for

[14] After reporting its concerns to the appropriate federal authorities and assisting them in their investigations of NMC's business practices, Ven-A-Care brought its first action under the Federal False Claims Act against NMC in June of 1994. Ultimately, the NMC action led to the United States recovering nearly $500,000,000 and W.R. Grace divesting itself of its healthcare businesses. [*Id.*; Exh. E, at 750:10-751:22]

nebulizer drugs such as those distributed by Defendants Dey and Roxane. [Exh. Q, Jones Tr., Oct. 8, 2002, at 115:17-120:23]. Ven-A-Care immediately alerted the appropriate government officials and focused its efforts on the inhalation drugs. By August 1997, VAC determined that it had sufficient information to allege that two manufacturers of nebulizer drugs, Defendant Dey and Defendant Warrick,[15] were knowingly reporting inflated prices that created inflated spreads and using them as an inducement for providers to purchase or dispense their drugs. Ven-A-Care amended its action against Dey in 1999 to include claims relating to ipratropium bromide after it discovered that Dey, and later Roxane, were creating inflated spreads for this product.

Ven-A-Care also possessed a community pharmacy license and had access to industry insider pricing and marketing information relating to self-administered pharmaceutical products. This enabled Ven-A-Care to assist first the Florida Medicaid Program and later the federal government to identify inflated spreads on these drugs. By mid-1999, Ven-A-Care concluded that Federal Upper Limits ("FULs") and other efforts to contain Medicaid program drug costs were being circumvented by inflated drug price reports by certain companies. [Exh. R, Lockwood 30(b)(6) Tr., Apr. 23, 2009, at 20:3-21:3; Exh. C, Exh. 2]. On July 9, 1999, Ven-A-Care informed Bill Shrigley of the OIG of its discovery that the FUL program was not protecting the United States from drug manufacturers' false, inflated prices and provided Mr. Shrigley with a series of charts reflecting spreads on drugs covered by the FUL program. [Exh. C, Exh. 2 at Tab 100]. This eventually led to Ven-A-Care's addition of various self-administered drug products to its action, such as the 17 gram Albuterol inhaler and ipratropium bromide inhaler.

[15] Warrick is a defendant in *United States of America ex rel. Ven-A Care of the Florida Keys, Inc, v. Schering Corporation, et al.*, MDL 1456, 01-12257-PBS.

By 2000, Ven-A-Care determined that the information it had received regarding additional drug companies and drugs, including certain self-administered drugs and Roxane's nebulizer-administered ipratropium bromide, supported another FCA *qui tam* action. In April of 2000, Ven-A-Care's principals met with representatives of the United States Attorney's Office for the District of Massachusetts regarding the additional fraud in the pharmaceutical marketplace. [Exh. S, Lockwood Tr., Mar. 17, 2008, at 589:8-591:15]. Long before including the drugs in an FCA action, Ven-A-Care provided the Government with the true prices available over time to Ven-A-Care for Dey's 17gm albuterol inhaler and refill and Roxane's ipratroprium bromide nebulizer drug and inhaler, the prices reported to the pricing compendia by Dey and Roxane and the resulting spreads, information about how the inflated spreads were marketed and an explanation of how the Medicare and Medicaid Programs were damaged. Examples of the prices provided to the Government prior to filing the Complaint in the District of Massachusetts are included in Exh. C, Exhs. 2, 4 & 5.[16]

Ven-A-Care was a continual source of industry insider pricing information and marketing evidence to DOJ and OIG, and its information was used by the Inspector General in preparing reports such as those published in June of 1996 (OEI-03-94-00393) "Suppliers' Acquisition Costs for Albuterol Sulfate" and in December of 1997 (OEI-03-97-00290) "Excessive Medicare Payments for Prescription Drugs" [Exh. T, Tawes Tr., Apr. 25, 2007, at 338:15-22, 339:1-5; Exh. U, Tawes Tr., Dec. 13, 2007 at 797:17-22, 798:1-12, 869:3-12; Exh. V, Vito Tr., Feb. 6,

[16] For public disclosure purposes, of course, it does not matter whether some of this information was known to the government. That type of government knowledge bar was legislated out of the FCA by the 1986 amendments. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 26 (1st Cir. 2009) ("Congress replaced the 'government knowledge' regime with one … focused on the 'public disclosure of information given to the government.'"); *United States ex rel. S. Prawer & Co. v. Fleet Bank*, 24 F.3d 320, 325-27 (1st Cir. 1994).

2008, at 1113:3-17, 1116:1-16; Exh. W, Vito Tr., June 20, 2007, at 604:16-22, 605:1-12; Exh. X, Molyneaux Tr., Jan. 11, 2007, at 247, 251:20-22, 252:1-10; Exh. Y, Ragone Tr., Apr. 17, 2007, at 124:20-125:8, 130:15-131:6], as well as by the Department of Justice in publishing the "DOJ AWPs" in 1999. [Exh. U at 811:3-13].

Even after filing the 2000 Massachusetts FCA action, Ven-A-Care continued its review of industry insider price information, such as wholesaler pricing data from McKesson and Bergen Brunswig, evidencing true transaction prices on Abbott's Erythromycin drugs. Using new analytical techniques, Ven-A-Care discovered inflated spreads between the prices reported by Abbott's PPD Division for these drugs and the transaction prices generally and currently paid. [Exh. Z, Lockwood Tr., Apr. 24, 2009, at 289:9-290:22; Exh. R at 22:14-26:16]. In 2000, VAC accessed non-public electronic information about the prices McKesson paid for the defendants' drugs through a system called Econolink and created a database and ratios in order to determine any inconsistencies between the non-public prices generally and currently paid by providers and the reported prices. *Id.* The VAC analysis showed that the bulk of the Abbott PPD drugs, or brand/oral drugs, had a 25% mark up or 1.25 ratio between transaction price and AWP. *Id.* However, the ratios for the Erythromycin drugs ultimately at issue in VAC's complaint were significantly higher. *Id.* Similarly, VAC discovered that the ratios between the reported WACs and the transaction prices were within a reasonable expected range for hundreds of Abbott PPD products except for Erythromycin drugs (most of which were branded products). VAC discovered that Abbott reported a false inflated WAC for the Erythromycin products and a substantially inflated AWP. *Id.*

Additionally, Ven-A-Care analyzed the impact of Abbott's inflated price reports for the Erythromycin drugs on the FUL. VAC determined that, had Abbott reported prices reflecting

prices generally and currently paid in the marketplace, the FUL would have been set at a significantly lower amount. *Id.* Further, it discovered that, had Abbott reported an AWP reflecting the marketplace in the same manner as the other PPD drugs, the AWPs for the Erythromycin drugs would have resulted in Medicaid reimbursement for ingredient costs at amounts below the FUL. [Exh. R at 22:14-26:16]. Again, Ven-A-Care provided its information about the Abbott Erythromycin products on an ongoing basis to the Government beginning in September 2000. [Exh. Z at 295:2-21]. VAC's attorneys detailed VAC's discovery of fraud with respect to Abbott's Erythromycin drugs in an October 23, 2000 letter and stated VAC's intent to amend its District of Massachusetts case to include allegations against Abbott for Erythromycin. [Exh. AA, VACMDL 90973-90975]. The letter included VAC's original source information about specific drugs, NDCs, market prices, reported prices and spreads. *Id*. Ven-A-Care also prepared and presented a power point presentation regarding fraud in the oral drug marketplace, including Abbott's Erythromycin drugs, in January 2001. [Exh. Z at 289:9-290:22]. VAC gave the McKesson Econolink databases to the Government on or about January 19, 2001 and made a presentation on the allegations against Abbott with respect to its Erythromycin drugs that would be filed in the First Amended Complaint. [Exh. R at 227:12-21; Exh. Z at 296:20-299:17].

III. ARGUMENT

The Defendants have failed to identify a single FCA-defined "public disclosure" upon which the actions against them are based. Instead, the purported "disclosures" they point to do not reveal the relator's allegations of fraud against specific defendants and fail to contain sufficient specific information from which one could determine the fraud, including the requisite knowledge by particular defendants. The defendants attempt to contort the assistance Ven-A-

Care provided to the government into a public disclosure. While DOJ and OIG used the information supplied by VAC in their investigations of Medicare and Medicaid reimbursement policies, they clearly elected to not disclose Ven-A-Care's allegations of fraud against a specific defendant perpetrator. Indeed, DOJ maintained the confidentiality of Ven-A-Care's allegations of fraud until it moved to unseal these actions in 2006 and 2007.

Even if the assistance Ven-A-Care provided to the government had resulted in public disclosures, Ven-A-Care is clearly an original source of the information. Ven-A-Care was able to expose and help the government investigate and prosecute the defendants' fraud scheme only because it is an industry insider with access to actual prices generally and currently paid over time, a party to which the unlawful inducements are directed, and willing and able to assist the government. DOJ, GAO, OIG, Congress and the states' attorneys general have all looked to VAC as a source of industry information about the fraud scheme. Indeed, even this Court noted that the New York Counties were able to eventually successfully plead a cause of action based upon falsely inflated AWPs only because they secured access to and used VAC's insider pricing information.[17]

The factual record developed in this litigation plainly demonstrates that this Court possesses subject-matter jurisdiction over VAC's *qui tam* actions.

A. **Ven-A-Care's FCA Actions Were Not Based Upon Allegations or Transactions That Were Publicly Disclosed**

Defendants randomly list more than 200 items which they apparently contend constitute public disclosures upon which the Relator's allegations are based; however, collectively,

[17] *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642, *15, fn 8 (D. Mass. 2007) (Court found that Ven-A-Care's pricing information – relied upon by plaintiffs New York City and forty-two New York counties – satisfied Rule 9(b)).

Defendants discuss only approximately 25 items specifically in their briefs.[18, 19] Of the items discussed, some do not derive from the requisite statutory sources to be classified as public disclosures; others contain only general references and information regarding the subject matter of government reimbursement; and still others did not appear in the public domain until after VAC had filed its sealed complaints against the defendants. Although it may be tempting to assume that a disabling public disclosure lurks somewhere within the piles of documents defendants submitted, careful analysis shows that the opposite is true. Accordingly, the items put forth by the defense do not divest this Court of jurisdiction over VAC's actions.

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[18] All items referenced in the briefs are listed in the chart provided in Exh. B, which sets forth why each document does not qualify as a public disclosure.

[19] Of the remaining items, which defendants did not discuss, there do not appear to be any disabling public disclosures. Many of the documents, for example, are not even public disclosures within the statutory definition of documents that can be considered. Thus defendants have listed numerous Myers & Stauffer studies conducted for state Medicaid programs. The majority of courts to have addressed this issue, however, have determined that the list of sources in § 3730(e)(4) is exhaustive and thus that state investigations or reports do not count. *E.g.*, *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 528 F.3d 292, 296 (4th Cir. 2008) (in addition to discussing statutory language, court concludes that state reports do not count as public disclosures since those reports often address only local issues and are not likely to have attracted public attention or consideration by the federal government). Defendants have also mixed in citations to various industry or government publications that are clearly not within the statutory definition of a public disclosure – for example, Red Book, HHS Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), the Pink Sheet published by the FDA and available in full only by subscription, and State Medicaid manuals. Additionally, there are approximately a dozen letters from states or others to HCFA, commenting on proposed rules or transmitting other information, that do not constitute public disclosures within the statutory definition. Many other itemized documents are OIG reports of various types, most of which suffer from the same issues as the reports this Court has already analyzed – they do not assert anything about fraud, they do not identify particular manufacturers, they do not provide specific prices or, at most, provide only snapshot prices for drug types, but not by NDC to allow manufacturer identification, and they present their analysis in terms of average price differentials, often revealing a wide range of spreads that make clear that not all companies are engaging in fraudulent price inflation.

A court need not decide if the Relator was an original source of the allegations unless it concludes they are based upon an FCA-defined public disclosure. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 728 (1st Cir. 2007). This Court recently analyzed the FCA public disclosure bar in a case where the pertinent facts and allegations were parallel to those of the present case.[20] *United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Actavis Mid-Atlantic, LLC*, 2009 U.S. Dist. LEXIS 92945 (D. Mass. Oct. 2, 2009); *see also United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, 538 F. Supp. 2d 367, 380-383 (D. Mass. 2008). The *Actavis* defendants pointed to similar government reports and other purported public disclosures in their unsuccessful assertion of the public disclosure bar. This Court's *Actavis* decision resolves most, if not all, of the issues raised by defendants in the present action.

1. Public Disclosure Determination

Only a disclosure from an enumerated statutory source (a criminal, civil or administrative hearing; a congressional, administrative or Government Accounting Office report, hearing, audit or investigation, or the news media) will trigger a possible public disclosure bar. 31 U.S.C. § 3730(e)(4); *United States ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 20 (1st Cir. 1990). As specifically set forth in Exhibit A, many of the purported "disclosures" put forth by the defense do not even fall within the categories specified in the FCA. A good example is state reports, such as those prepared by Myers & Stauffer. The FCA Public Disclosure Bar does not include such state reports, or publications of limited distribution, even if they are available to the public. In this regard, the defendants have failed to establish that the state reports were made public and, of course, those reports did not include specific drug and company information. *E.g., United*

[20] The *Actavis* action involves seven defendant groups that were originally joined in the relator's sealed Boston FCA action.

States ex rel. Wilson, 528 F.3d at 296. The state items presented by defendants are often a mixture of working papers, draft reports and possible final work products that ordinarily presented averages and single point-in-time information that is not NDC specific and never contains allegations of fraud by anyone, let alone a specific company. Additionally, there is no showing as to what parts of the reports and backup were made public or provided to the U.S.

Utilizing the much-cited guidance provided by *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994), this Court in *Actavis* reduced the public disclosure determination to an elementary mathematical formula, explaining the primary components of each element of this formula. *Actavis*, 2009 U.S. Dist. LEXIS 92945 at *9-10.

> [I]f X+Y=Z, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed. Under the framework, X stands for the allegedly false set of facts set forth in the claim at issue, and Y is a proxy for the allegedly true set of facts. Thus 'when X [the false set of facts] and Y [the true set of facts] surface publicly, or when Z is broadcast … there is little need for qui tam actions' and the claim will be barred.

Actavis, 2009 U.S. Dist. LEXIS 92945 at *9 (*quoting West*, 538 F.Supp. 2d at 383 *(quoting Springfield Terminal Railway*, 14 F.3d at 654 (citations omitted)). VAC will apply this Court's formula to the defendants' purported public disclosures.

In *Actavis*, this Court found the "Z" (the allegation of fraud) was not "broadcast" because the government reports lacked any suggestion of fraudulent activity by any drug manufacturers and merely noted an average difference between reported AWP and invoice or acquisition cost. *Actavis*, 2009 U.S. Dist. LEXIS 92945 at *10. The reports contained no "Z" because they lacked any "discussion about the reason for these differences or any suggestion of wrongdoing by anyone" and lacked any "discussion or suggestion that AWPs are being used as part of a scheme

to defraud the government, or any indication of how the scheme works - using Medicaid payments grossly inflated by fraud as a promotional tool for drugs." *Id.*

The alleged disclosures lacked the requisite "Y" element because they failed to disclose the central issue: "that AWP and WAC were so inflated, they 'could hardly even be called true list prices,' that the 'discounts' taken off AWP were frequently larger than the price providers actually paid." *Id*. (*citing Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008)). Further, the government reports did not point to the existence of the "mega-spreads at the heart of this case," or to the fact that they were being used as a marketing tool to promote drug sales. *Actavis*, 2009 U.S. Dist. LEXIS 92945 at *14-15.

The same is true in this round of briefing. These Defendants present this Court with a multitude of documents and reports they contend constitute public disclosures. However, like the *Actavis* defendants, Dey, Roxane and Abbott also fail to correctly apply the legal principles stated in the cases they rely on. As this Court said in *Actavis*:

> More importantly, even if the Defendants were right about the law, they are wrong about the facts. The Defendants and the drugs at issue are not readily identifiable from the generalized discussions of averages in the reports. Many manufacturers and drugs could be (and likely are) innocent of the conduct alleged here, and unrelated to the averages discussed in the reports. While some of the documents pointed out by the Defendants discuss AWP and WAC in generalized industry-wide terms, none of the reports allege or disclose industry-wide wrongdoing, and the differences between AWP and actual acquisition cost are reported as average figures. Which drugs and which manufacturers caused the averages to be at the levels reported are not disclosed by any of the reports, and the Defendants and the drugs at issue are not readily identifiable from them.

Actavis, 2009 U.S. Dist. Lexis 92945 at *10-11.

2. Application of *Springfield Terminal/Actavis* Road Map

a. Chart of items

For convenient reference, the chart provided in Exh. B catalogs the pertinent information about each of the approximately 25 items discussed in the defendants' briefs. The chart provides a concise summary of the contents of each item and identifies the critical elements necessary for the Court's determination whether each item constitutes a public disclosure.

b. Cited Documents

i. OIG reports

Like OIG reports considered previously by this Court in the context of purported public disclosures, the OIG reports cited by these defendants simply do not contain VAC's allegations of the defendants' fraud scheme ("Z") or the essential elements of the underlying fraud (true prices and vastly inflated false price; or "X+Y"), from which fraud can be inferred.

While most of the presented OIG reports reflect concern by HHS-OIG and HCFA or CMS that AWP is an unreliable basis for estimating providers' actual acquisition costs for drugs and indicate, generally, that Medicare and some Medicaid programs have over-reimbursed providers for some drugs because they failed to discount sufficiently from AWP in estimating acquisition costs (an attenuated "X" element), the OIG reports completely fail to ascribe blame, let alone fraudulent behavior, to any drug manufacturer, nor do they specify prices, requisite "Y" elements. As in *Actavis*, the OIG and other government reports also did not report that any possible wrongdoing implied by the price discussions could be attributed to all drug manufacturers, or even all generic manufacturers. To the contrary, the reports often disclosed a wide range of price differentials, suggesting that not all companies reported AWPs in the same manner or inflated their prices to gain marketing advantages. As in the court held in *United*

States ex rel. Cericola v. Fannie Mae, 2007 U.S. Dist. LEXIS 95783 at *3-4 (C.D. Cal. 2007), "the mere disclosure of relevant information in the public domain is not enough to trigger the bar." In that case, the series of public reports focused on fraud perpetrated against borrowers who had been saddled with loans for home improvement projects they could not afford and were of substandard workmanship, but that did not focus on allegedly false insurance claims against the government. The court accordingly found that "the connection between the publicly reported information and the fraud alleged in the present lawsuit is too attenuated to implicate the FCA's public disclosure bar." *Id.* at *5. Similarly, in *Little ex rel. United States v. Eni Petroleum Co.*, 2009 U.S. Dist. LEXIS 64697 (W.D. Okla. 2009), defendants submitted many purported public disclosures from congressional hearings, GAO reports and other administrative reports, news media articles, and civil litigation, and the disclosures mentioned transportation costs and royalties on oil production. However, the submitted reports did not reveal a fraud involving oil companies improperly deducting the transportation costs from the royalties due on oil production they paid to the government, and hence they were rejected as public disclosures. Id. at *5-6.

As in *Cericola* and *Little*, VAC's detailed allegations that specific manufacturers knowingly reported vastly inflated prices for specific drugs to the publications relied upon by government payors to create reimbursement incentives in aid of marketing efforts, stand in sharp contrast to the published reports and cannot fairly be said to be based upon any of them.

ii. Industry trade publications

Limited-circulation industry trade publications cited by defendants are not traditional "news media," a term ordinarily applied to newspapers, general-circulation magazines, and radio and television sources. Nevertheless, should the Court elect to accord such specialized, insider publications traditional "news media" equivalency for purposes of analysis, the examples cited

by the defendants do not contain allegations of fraud ("Z") and only generally discuss problems with the then current Medicaid reimbursement model. Moreover, these articles do not include the true set of facts ("Y"), such as the particulars of this case, or any false prices ("X"), from the juxtaposition of which elements of fraud could be inferred.

For example, Abbott Exh. O – July 1980 article in *Modern Healthcare* titled "Hospitals Play Into Hands of Vendors Who Try to Break Group Contracts" – contains nothing of relevance. This article is entirely focused upon hospital group negotiating tactics. The *only* pricing information mentioned is hospital pricing. As Ven-A-Care notes in the Abbott section below regarding Dr. Vladeck's vague memory of a *Modern Healthcare* article on IV solution pricing (which might be this article), the best Abbott could find after its "manual search of a decade's worth of back issues" was this article discussing exclusively hospital pricing in 1980 (Abbott Mem. at 16, n.7). There is absolutely no indication in this article that any such pricing was available to retail pharmacies. To the contrary, Ven-A-Care has shown that another of Abbott's alleged public disclosures actually proves that retail pharmacies did not have the ability to purchase at lower hospital pricing levels. (*See* Abbott (Ery) MTD Exh. 11 (a misleading, incomplete excerpt) compared to Dkt. No. 6625, Anderson Decl. Ex. 26 (a full copy).). This July 1992 Congressional record proves a prominent retail pharmacy trade group, the National Association of Retail Druggists ("NARD"), testified before Congress and swore "hospital" prices were not available to retail pharmacies. (*See id.* at pp. 286, 295 and 301). In fact, the NARD complained that its retail pharmacy members "were getting a raw deal." *Id*. at 301.

Similarly, Abbott Exh. P – Nov. 1994 Drug Topics "LATELINES" – consists of merely one paragraph which notes HCFA will seek pricing data from pharmacies. This statement about alleged future activities of HCFA does nothing to disclose any pricing information at all, much

less pricing information about a given drug company's products or, more importantly, a particular drug. The snippet does not even note a generalized discrepancy between pricing and AWP.

Because these trade publications contain nothing resembling VAC's specific and detailed allegations of fraud, or VAC's examples of true prices and false-price reporting schemes, these articles do not disclose the transactions or allegations on which VAC's complaints are based.

iii. Press releases by Congressman Pete Stark

Whether bare copies of a Congressman's press releases, absent evidence of publication in any statutory source, qualify for consideration in a public disclosure analysis is doubtful. Nevertheless, should the Court elect to consider them, the document dated September 2, 1999 ("AWP = Ain't What's Paid") names no drug manufacturers, identifies no drugs, specifies no prices and does not suggest that an entire industry is guilty of fraud. Plainly, it did not publicly disclose the allegations upon which VAC's complaints were based. As discussed *infra* under "Specific Arguments Relating to Roxane," the data in the press release dated September 1, 1999 ("Drug utilization soars as profits soar") was provided to Congressman Stark by Ven-A-Care. In any event, while the document does identify ipratroprium bromide, generally, as declining in cost to providers while Medicare reimbursement remains unchanged, it contains neither "Z" nor "X+Y." It does not contain VAC's specific allegations against specific manufacturers and the pricing of particular drugs, and VAC's complaint is not based upon it.

iv. Newspaper and magazine articles

(1) Lexington Herald- Leader, July 5, 1987: "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars"

Defendants would have this Court believe that this article spelled out the entire case against these companies. But this article does not mention any of the Defendants or drugs at issue in this action and, at most, asserts only that there are some companies playing a spread game. It does not reveal the true prices and false prices ("X+Y") contained in VAC's detailed and specific complaints. It identifies only two drug manufacturers (neither of which is a defendant in this case) as having "listed" the AWP of one drug each (neither of which is a subject drug) at substantially more than the cost to a provider. The article is highly critical of Medicaid's reimbursement system, pointing out that Medicaid programs have to rely on pricing information that in most cases is provided to the pricing publications by the drug companies. A sympathetic official of a generic drug manufacturer (not a party to this case) is quoted as saying that "many" companies have abused AWP. A Florida Medicaid official is quoted as saying the system "penalizes companies that have low markups between their direct prices and [AWP]." According to the article, "some companies are exaggerating [AWP] as a sales technique" called "playing the spread."

Arguably, this little-noticed article from 1987 in a small media market constituted some disclosure of possible fraud similar to that later alleged by VAC. But several elements dictate that this not be deemed a disabling public disclosure sufficient to bar VAC's 1995, 1997 and 2000 allegations of fraud against Abbott, Dey and Roxane. First, none of these companies were mentioned in the article, nor were their drug groups or direct competitors referenced. Second, the Lexington Herald article itself was equivocal at best as to whether the conduct it was describing

was simply a by-product of the AWP system or likely fraud. For example, the article quotes a state Medicaid official as saying that "there wasn't sufficient evidence of wrongdoing for any prosecutions." Third, the article, in the manner of most of the OIG reports from that era, did not fully distinguish between deliberate mega-spreads and more routine failure to include industry-wide discounts, which lead to the type of differences that the cited OIG report found – AWPs that were 16% "too high." No information was provided to allow the government to determine who the wrongdoers were, if anyone at that time. Fourth, the federal government adopted new Medicaid regulations in 1987 which were designed to deal with certain drug pricing issues and could have been thought to have dealt with any wrongdoing from that time period. Finally, it is critical to take into account the date of that article, long preceding VAC's defendant- and drug-specific allegations and even preceding the marketing of some of the generic drugs at issue in these cases. *See Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1048 (8th Cir. 2002) ("The independent knowledge requirement clearly serves the congressional goal of barring parasitic actions, but it is worth noting that it does not bar actions based on old news."). In this sense, the article can only be held to have foretold possible additional fraud in the future. If the Public Disclosure Bar were applied to such broad generalities from the past, particularly where the purported disclosure did not name wrongdoers or the wrongdoing hadn't yet occurred, it would lead to the absurd result of entire industries escaping FCA actions by most relators based upon a "blast from the past" by some reporter in some newspaper who discussed the potential for a certain kind of fraud in a particular industry. The clear goal of the False Claims Act – to protect the public fisc from abuse by government contractors and the like – would be ill-served by such an application. *See, e.g., United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, 2009 U.S. Dist. LEXIS 42612 (S.D. Ohio 2009) ("The Court therefore

does not see how the creation of extra barriers and disincentives for whistleblowers to report fraud comports with Congressional intent, which is that whistleblowers aggressively 'fish' for evidence of fraud on behalf of the government.")

(2) Barron's magazine, June 15, 1996: "Hooked on Drugs"

The June 1996 Barron's article identifies by name Abbott's Vancomycin and solutions, and specifies the reported AWPs, the wholesale prices and percent prices under AWP. It is not a disabling public disclosure, however, because it was published approximately a year *after* VAC filed its action against Abbott naming these drug products. Although the article may allege sufficient information to constitute a public disclosure with regard to Abbott, VAC had already provided its information to the government and on June 23, 1995 filed a Federal action in Miami including its claims against Abbott. See discussion, infra, regarding Abbott-specific arguments. Neither Dey nor Roxane were mentioned or implicated in any fashion in the *Barron's* article.

v. Radio Address by the President of the United States

President Clinton's weekly radio address on "waste, fraud and abuse" in Medicare fails to satisfy the public disclosure elements because it lacks the "X+Y" elements and a "Z" product. President Clinton's address simply criticizes Medicare's AWP reimbursement system in general terms and calls for reform, suggesting that there may be no illegality, but only institutionalized shortcomings in the program's established systems and processes . The address named no drug manufacturers, identified no drugs and accused no one of fraud. VAC's complaint simply cannot be deemed to have been based upon this public radio address.

vi. State-Case Complaints

The state complaints asserted by Roxane as public disclosures are all dated subsequent to this action making similar allegations against Roxane and the other defendants which was filed

on April 10, 2000, and thus are not a prior public disclosure of VAC's allegations against them. With regard to Roxane's contention that the unsealed Texas action and the publicly filed complaints by other states pose jurisdictional obstacles to VAC's addition of certain Roxane drugs to VAC's already pending federal action, Roxane confuses the jurisdictional requirements pertaining to a cause of action with the mere addition of other drugs that were part and parcel of the same fraudulent pricing and marketing scheme by the same manufacturer, marketing division, marketing personnel and price reporting personnel as in the original action. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007). The addition of such other drug products in this context does not constitute a new action for purposes of the public disclosure bar.

B. Ven-A-Care Clearly Qualifies As an Original Source

Relator's FCA actions are clearly not based upon a public disclosure as defined by the FCA. However, even if each of the Relator's actions were so based, this Court would possess subject-matter jurisdiction because VAC is an original source. Essentially, defendants argue that VAC is not an original source because its information was not direct and independent, but instead was derived from secondhand sources and collateral research. Additionally, Abbott questions whether VAC provided its information to the government prior to filing suit.[21]

Ven-A-Care's direct and independent information included its knowledge of true transaction prices in the marketplace over time and from which it could determine the prices generally and currently paid for particular drugs; its knowledge of the marketplace and methods by which price and spread information is communicated by and on behalf of manufacturers to Medicare and Medicaid providers; and the results of its monitoring this information over time

[21] Abbott does not actually argue that VAC did not provide the required information to the government, but merely that it has not been able to evaluate whether this requirement was met. Abbott Mem. at 4. VAC has resolved any possible issue in this regard with the Jones Declaration, *see* Exh. C.

and comparing it with the Defendant's reported prices and marketing techniques. Ven-A-Care was thus able to conclude that the Defendants acted "knowingly" under the False Claims Act. Defendants would be hard-pressed to argue that any of this price information was "public" since they have fought vigorously in this litigation to establish the confidentiality of these drug prices. As defendants noted in that context, their contracts with wholesalers or retailers stipulated that the prices were confidential. Further, only pharmacies that could respond to Defendants' reimbursement inducements received the advertisements and materials that promoted the reimbursement spread. The information essential to these FCA actions was clearly industry insider information to which Ven-A-Care had direct and independent access.

The allegations about Dey's inhalant medications provide an excellent example. In August 1995 VAC was encouraged to enter into a business arrangement where it would benefit from the inflated spreads on Dey's nebulizer products. While VAC immediately reported this information to the government, it did not immediately amend its FCA action to allege that Dey was knowingly making false statements actionable under the False Claims Act. Indeed, this single point in time mega-spread situation could have resulted from rapidly falling prices and truthful, albeit lagging, price reports. However, after observing the information directly available to it for two years, VAC was able to conclude that Dey was not taking action to cause its reported prices to be truthfully representative of the prices generally and currently paid in the marketplace and that, instead, it was creating mega-spreads and causing them to be marketed directly and through organizations with which it contracted. By August 1997, VAC had sufficient information to allege knowledge and joined Dey in its existing FCA case in federal court in Miami. VAC also clearly meets the disclosure requirement of the original source

exception because it began to inform the government of Dey's conduct immediately upon discovering it in August 1995, and up to and after the time that it commenced its action.

Satisfaction of the "original source" provision of the FCA turns on a relator having direct and independent knowledge of information underlying his allegations. "Direct" generally means based on plaintiff's own labors, *United States ex rel. O'Keefe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 95 (D. Mass. 2001), and "independent" means separate from the public disclosures. *Id.* Notably, this does not require the relator to have direct and independent knowledge of every detail or element of its complaint. *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1050 ("To qualify as an original source, a relator does not have to have personal knowledge of all elements of a cause of action."); *Springfield Terminal Railway*, 14 F.3d at 657 & n.4 (A relator possesses the requisite knowledge under the statute if the relator has "direct and independent knowledge of any essential element of the underlying fraud transaction.") Additionally, as numerous courts have noted, the statute requires that relator be "an" original source, not "the" original source. *E.g., United States ex rel. Ervin & Assoc., Inc. v. The Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 39-40 n.11 (D. D.C. 2005) ("use of the word 'an,' … suggest[s] there may be more than one original source eligible to bring suit ….").

Defendants argue that the fact that some of Ven-A-Care's price information came to it through group purchasing organizations or First DataBank demonstrates that this information was not directly obtained by VAC (*e.g.*, Abbott Mem. at 9.). Defendants also contend that VAC cannot qualify as an original source because it did not transact business with each of the defendants for each of the drugs at issue. Notably, none of the defendants cite any case that disqualifies a relator as not having "direct and independent knowledge" based on the arguments defendants advance. No authority is cited to support that interpretation of direct and

independent. Cases refer to information obtained secondhand through another employee or from relator's lawyer, *e.g.*, *Natural Gas Royalties Qui Tam Litig. v. Pac. Gas & Elec. Co.*, 562 F.3d 1032, 1046 (10th Cir. 2009), *cert. denied*, 2009 U.S. LEXIS 5970 (2009) (notes indicated that Relator or his staff confirmed through interviews that Defendants used one or two specific measurement practices that were the subject of the *qui tam* complaints, "this secondhand knowledge from employees of various Defendants does not constitute 'direct and independent' knowledge"); *United States ex rel. Barth v. Ridgedale Elec.*, 44 F.3d 699, 703 (8th Cir. 1995) (union's knowledge of the false nature of the employer's reports was not sufficiently "direct" to give the union "original source" relator standing because the union agent derived his information from visits to the worksite, copies of public payroll records and interviews with employees, but also holding that the inside employee who knew about the fraud was an original source); *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 921 (7th Cir. 2009) (relator did not have direct and independent knowledge where "she had no knowledge whatsoever of the fraudulent conduct before hearing from an attorney"); *Battle v. Bd. of Regents*, 468 F.3d 755, 763 (11th Cir. 2006) (information which relator obtained through interviews with rail maintenance and fueling personnel at an MBTA/Amtrak facility, engineers at General Motors electro-motive division, a representative of the EPA Fuel and Vehicle Emissions Research laboratory, and a Harvard School of Public Health professor, as well as an analysis of admittedly public data, did not constitute direct and independent knowledge), but do not turn on whether there was a publisher involved in the transmission of the information.

As the VAC principals explained in detail at deposition, the normal business operations of a small pharmacy involve participation in GPOs, and the normal business function of those GPOs includes negotiation of prices for the members. The transmission of those prices to the

members is accomplished through publications of the GPO. Likewise, pharmacies routinely obtain information about published prices for manufacturer's drugs through pricing compendia such as FDB. The financial inducements created by the Defendants' mega-spreads are directed at providers, including VAC. The Defendants' scheme was based upon the fundamental premise of creating inducements for providers who would in turn bill Medicaid or Medicare. These inducements were directed at one particular type of entity, the pharmaceutical provider, and the provider had direct information and knowledge about the inducements being directed to it.

Ven-A-Care, as a small pharmacy, was well-positioned to observe firsthand the prices generally and currently paid in the marketplace and the comparative inflated false price representations made by the Defendants for the subject drugs. In addition, Ven-A-Care was in a position to receive, and observe the means by which the Defendants communicated, the mega-spreads to providers through their co-actors in the marketplace such as wholesalers and group purchasing organizations. The defendant manufacturers contracted directly with GPOs, distributors and wholesalers to facilitate the sales of their drug products and the communication of the pricing and spread information to providers.

That FDB or a GPO transmitted what became a key part of the fraud puzzle does not equate to those entities having been the direct source of information that there was a fraud. FDB or the GPO was simply the transmitter of some of the information that established or constituted the fraud; it was decidedly not the discoverer of the fraud who alerted Ven-A-Care to the wrongdoing. The fact that Ven-A-Care did not directly purchase each drug at issue is similarly not relevant to an original source inquiry. Defendants ignore the fact that the FCA indisputably confers standing on relators based on their information and their right to recover a portion of the government's damages, not on whether or not they have suffered a direct injury or participated in

business transactions akin to the ones that constitute the fraud on the government. *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000) ("[T]he FCA can reasonably be regarded as effecting a partial assignment of the government's damages claim", upholding constitutionality of relator status under FCA); *United States ex rel. Farmer v. City of Houston*, 2005 U.S. Dist. LEXIS 18387 (S.D. Tex. 2005) *cert. denied*, 129 S. Ct. 570 (2008) (irrelevant that relator did not qualify under government home repair program in which fraud occurred).

Defendants also argue that VAC does not qualify as an original source because it obtained its information from "collateral research" and analysis of existing data. *See* Abbott Mem. at 9; Rox. Mem. at 16-17. But defendants are unable to cite any authority for the proposition that analysis of public files or data, when spurred by the whistleblowers' own observations and knowledge, defeats original source status. To the contrary, where a relator has information that it learned directly and independently of the public disclosures, the courts have recognized the critical role served by the relator who used that information to conduct research into the suspected fraud and possibly even confirmed that fraud through use of some public information. Because this is typically a very fact specific inquiry, plaintiff will describe in some detail the types of investigative relators who have been properly lauded by the courts:

> Erwin is the original source of the information alleged herein, insofar as Erwin has brought to bear its intimate knowledge of HUD operations, its observations and analyses of the mortgage loan auctions, its discussions with certain HUD employees and Wall street bidders, as well as its independent analyses of HUD's responses to numerous Freedom of Information Act requests. Amended Compl. at p. 18.
>
> * * *
>
> Erwin has "direct knowledge" of any information gleaned from direct observation and analysis, as that information was acquired without any "intervening agency." *Alexander*, 924 F. Supp. at 300. As for Erwin's discussions with individuals and its investigation, courts have allowed a plaintiff to proceed with a qui tam suit based on information uncovered during an investigation undertaken by that same

> plaintiff. For example, in Springfield Terminal Railway Co., the D.C. Circuit held that the plaintiff qualified as an original source when it obtained essential information through "its own efforts and experience, which … included personal knowledge of the [] proceedings and interviews with individuals and businesses identified in the []records." 14 F.3d at 657.

United States ex rel. Ervin & Assocs. v. Hamilton Secs. Group, Inc., 332 F. Supp. 2d 1, 7-8 (D. D.C. 2003).

The Tenth Circuit's evaluation of a legitimate whistleblower in *Kennard v. Comstock Res., Inc.*, 363 F.3d 1039 (10th Cir. 2004) is of a similar nature:

> The district court concluded that "Relators have merely compiled public information and because of their education and background were able to speculate that [Comstock] underpaid [] royalties." Aplt. App. at 498. We disagree…. The district court further relied on the fact that Relators used documents already in the public domain during their investigation. However, in the instant case, **Relators' claim did not derive from a third party's research and investigation. Relators discovered the alleged fraud and Relators conducted the investigation….** It is important to note that none of the public documents disclosed the alleged fraud. It was only through independent investigation, deduction, and effort that Relators discovered the alleged fraud. Relators "had direct and independent knowledge of the fraud allegedly committed [since they are] the [people] responsible for ferreting it out in the first place." *Holmes*, 318 F.3d at 1207. **Relators were not just assemblers of information. This case would not exist but for Relators sniffing it out.** Through discovery and deduction, Relators ferreted out the alleged fraud in this case and must, therefore, qualify as an original source.

Id. at 1046 (emphasis added). *See also Cooper v. BlueCross & BlueShield*, 19 F.3d 562 at 564, 568 (11th Cir. 1994) (*qui tam* plaintiff was considered an original source because his investigation first alerted HCFA to specific violations of Medicare Secondary Payer law by Blue Cross Blue Shield of Florida).

The fraud that VAC brought to the government's attention was materially different than the government's mere identification of overall differences between invoice prices and published prices for pharmaceutical products in general. Generalized differences at a point in time may be cause for further investigation; however, they in no way accuse anyone of fraud or identify the

fraudsters. This is a far cry from public disclosures of allegations and transactions. *See United States ex rel. Heath v. Dallas/Fort Worth Int'l Airport Bd.*, 2004 U.S. Dist. LEXIS 11301 (N.D. Tex. 2004) ("There is a difference, however, between what could potentially happen – which is what the 1994 SWP3 Update and the Chiang Patel Report describe – and what actually is happening – which is what the Engineering Site Visit Report shows").

Second, it is obvious in retrospect that much of the differential noticed by the government in its early reports was merely the result of an essentially formulaic spread between wholesale acquisition or invoice prices and published AWPs. Even as the government began to apply formulaic relationships to its reimbursement procedures, there was no public disclosure that certain drug makers were fraudulently exploiting the government's reliance on those formulas to create financial inducements through inflated spreads. No disclosures, except those made by Ven-A-Care, "put the government on the trail of" the AWP inflated spread fraud that VAC alleged. Even in the face of various investigative audits showing that, on average, transactional or invoice prices were lower than published prices, it is indisputable that Ven-A-Care's industry insider pricing and marketing information "demonstrate[d] a new and undisclosed relationship between disclosed facts, that puts a government agency 'on the trail' of fraud, where that fraud might otherwise go unnoticed." *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 179 (5th Cir. 2004). VAC had direct and independent knowledge of this information and provided it to the government prior to filing its lawsuits. Furthermore, it was only VAC's particularized price information and analysis of pricing and marketing conduct that allowed identification of specific manufacturers. *Cf. United States ex rel. J. Cooper & Assocs. v. Bernard Hodes Group, Inc.*, 422 F. Supp. 2d 225, 236 (D. D.C. 2006) ("Although the plaintiff may have communicated vague suspicions of fraudulent practices by unnamed entities,

it was the OIG that uncovered, through its own investigations, the identities of the alleged perpetrators and the exact circumstances of their allegedly fraudulent acts.").

In the event that this Court determines that there had been a disabling public disclosure, therefore, the Court's subject-matter jurisdiction over relator's complaints is preserved because VAC is an original source of information underlying its complaints.

C. Ven-A-Care, as a Corporation, Can Be an Original Source

Defendants argue that, while a corporation can be a relator, it cannot be an original source. The Defendants' contention makes no logical sense and the defendants cite no case holding that a corporation cannot be an original source under the FCA. To the contrary, corporations have been held to be an original source, *Springfield Terminal Railway*, 14 F.3d at 657; *see also*, *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 562 F.3d 295 (4th Cir. 2009); *United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496 (6th Cir. 2008); *United States ex rel. Huangyan Import & Export Corp. v. Nature's Farm Products*, 2004 WL 74310 (S.D.N.Y. 2004) (corporate plaintiff not an original source because complaint information was publically disclosed); *United States ex rel. Ervin and Associates*, 332 F. Supp. 2d 1; *United States ex rel. S. Prawer & Co.*, 24 F.3d at 322.

Defendants' argument is curious given that each has been sued "by and through" the individual officers of Ven-A-Care. Plainly Messrs. Jones, Lockwood, Cobo and Bentley can be original sources. Should the Court choose to consider the issue, however, the suggestion that VAC as a corporation can not be an original source should be rejected. As noted by the court in *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1048 n.12, nothing in the legislative history of the 1986 amendments to the FCA suggests that Congress intended to disqualify corporations from being an original source:

> But if examination of a statute shows "no plausible reason why Congress would have intended to provide for . . . special treatment of actions filed by natural persons and to have precluded entirely jurisdiction over comparable cases brought by corporate persons," *Clinton v. City of New York*, 524 U.S. 417, 429, 141 L. Ed. 2d 393, 118 S. Ct. 2091 (1998), the word "individual" does not limit the statute's scope to human beings. *Id.* Neither the 1986 Amendments Act nor a review of its background or legislative history suggests that Congress meant to exclude suits on the basis of whether the relator was a natural person, corporation, or association. We therefore reject this argument.

It would not make sense for the statute to permit a corporation to be a relator, but not an original source. Further, as the *Alina* court went on to explain :

> … it would have been odd to disqualify them only in the event that their claims were publicly disclosed before they filed suit, but that would be the effect of the interpretation defendants propose., *id*.[22]

Section 3730(e)(4)(A) itself provides an exception to the Public Disclosure Bar if a "'***person***' bringing the action is an original source." § 3730(e)(4)(A) (emphasis added). It is illogical to assume that the word "individual" was deliberately used in Sec. 3730(e)(4)(B)'s definition of original source as a limitation to the clear statement in subsection (A) that a person can be an original source. Courts have recognized that in interpreting Section 3730(e)(4) they should be "hesitant to attach too much significance to a fine parsing of the syntax", *United States ex rel. Mistick PBT v. Housing Auth.*, 186 F. 3d 376, 388 (3d Cir. 1999). *Accord*, *Glaser*, 570 F.3d at 917 (noting that Sec. 3730 (e)(4) is "hardly a model of careful draftsmanship"). The *Glaser* court discussed several other examples of language in that section which, if read literally, would lead to "baffling results" in terms of original source. These included a reference to public disclosures as including audits by the "Government Accounting Office" but not the General

[22] Plaintiffs' argument would also prevent a State, which can be a relator, *United States ex rel. Hartigan v. Palumbo Bros., Inc.*, 797 F.Supp. 624 (N.D. Ill. 1992) from being an original source where there was a public disclosure.

Accounting Office as well as to information obtained from criminal and civil "hearings" but not trials. *Id.*

The FCA is to be construed broadly to effect its purposes. *See Jefferson County Pharmaceutical Ass'n, Inc. v. Abbott Laboratories*, 460 U.S. 150, 103 S. Ct. 1011, 1018 (1983); *Arnold v. UPS*, 136 F.3d 856, 861 (1st Cir. 1998). The interpretation urged by Defendants would result in an unreasonable conclusion at variance with the intent of the Senate in amending the *qui tam* provisions "to encourage more private enforcement actions." S. Rep. No. 99-345 (1986), 1986 U.S.C.C.A.N. 5266, 5288. Thus, this Court should follow the purpose of the Act rather than a restrictive interpretation that contradicts an earlier section, *Perry v. Commerce Loan Co.*, 383 U.S. 392 (1966), and find that the corporate plaintiff VAC can be an original source.[23]

D. Specific Arguments Relating to Abbott

Inexplicably, Abbott argues that this Court should ignore the clear statutory directive – backed up by uncontradicted case law support – that the inquiry for relator jurisdiction proceed in a set order, evaluating public disclosure first, and only proceeding to original source if a public disclosure has been shown upon which the action was based. *See United States ex rel. Rost*, 507 F.3d at 728 (since no public disclosure, court need not address whether relator falls within original source exception); *United States ex rel. Duxbury*, 579 F.3d at 21. This progression is applied regardless how apparent it may be that a relator may not have been an original source of the information. *E.g., United States ex rel. Whitten v. Cmty. Health Sys.*, 575 F. Supp. 2d 1367,

[23] In the event that the Court should conclude that a corporation cannot be an original source, Ven-A-Care respectfully requests leave to amend its pleadings to change the description of the Relator such that its individual officers' and directors' names are substituted. Ven-A-Care was careful to include its officers and directors in its original and amended complaints. Ven-A-Care respectfully submits that the liberal policy relating to amending pleadings, particularly where substitution of a party or re-identification of a party can cure a jurisdictional defect, is appropriate in this case.

1376 fn.7 (S.D. Ga. 2008) (even where relator conceded that it could not satisfy "original source" requirements, court does not base its relator jurisdiction inquiry on that basis because there was no public disclosure shown).

Accordingly, Relator will first address the lack of a disabling public disclosure of the allegations and transactions underlying the fraud perpetrated by Abbott.[24]

Abbott's arguments as to the failure of VAC to establish jurisdiction are faulty on practically every level. Initially, Abbott has not identified a disabling public disclosure, with the possible exception of the 1996 Barron's article, which both post-dates Ven-A-Care's original complaint naming Abbott and of which Ven-A-Care was indisputably an original – albeit indirect – source of the critical information. Notably, the Barron's article itself alludes to Ven-A-Care – as the industry insider that is considering litigation concerning the inflated prices. The *Barron's* article itself was spurred by the OIG's June 1996 report relating to nebulizer drugs and the reporter's apparent inquiries of various government sources who disclosed to the reporter information reported by VAC or derived from investigations that Ven-A-Care's information had assisted. The article itself, of course, was published in 1996, about one year *after* VAC's 1995 complaint naming Abbott as the lead defendant, listing the drugs at issue in this case.[25]

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[24] Although the defendant-specific sections overlap to some extent with prior sections of the brief and with each other, Relator believes that it was important to respond to each defendant's main arguments in an identifiable section of this brief.

[25] Although VAC inadvertently omitted Abbott from one of its early amended complaints, this Court has held in a related context that there could be no dismissal of an entire action against a defendant if the United States had not consented. *United States ex rel. Ven-A-Care v. Abbott Laboratories, Inc.*, 538 F. Supp. 2d 392, 397 (D. Mass. 2008) (regarding dismissal of acyclovir claims). In any event, "the factual allegations in Plaintiff's original complaint are evidence of what information or knowledge Plaintiff had apart from any public disclosure." *United States ex rel. Dugan v. ADT Security Svcs., Inc.*, 2009 U.S. Dist. LEXIS 89701, *24 (D. Md. Sept. 29, 2009).

Abbott concedes that VAC's 1995 complaint pled the inflated AWP fraud, and Abbott is wrong when it claims that the complaint did not plead the inducement theory of fraud. To the contrary, the 1995 complaint plainly alleged that "[t]he grossly excessive Medicare and Medicaid reimbursement rates available to suppliers and physicians for the pharmaceuticals in question acted as an inducement to suppliers and physicians to purchase said pharmaceuticals from the manufacturers or distributors who had caused the Medicare and Medicaid programs to establish [these] reimbursement rates …." *US ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott et al*, 95-1354, USDC, S.D. Fla. (¶ 44).[26] Thus, the *Barron's* article merely disclosed what VAC's sealed FCA complaint already on file in the Southern District of Florida already alleged, together with some information apparently learned from government sources concerning information VAC had provided to the government.

Another of Abbott's alleged public disclosures was the government's 1994 investigation of drug prices, which Abbott concedes was not concluded prior to VAC's complaint. "The mere existence of an administrative investigation or report is not enough to trigger the jurisdictional

[26] In full on this point, the 1995 complaint alleged as follows: The grossly excessive Medicare and Medicaid reimbursement rates available to suppliers and physicians for the pharmaceuticals in question acted as an inducement to suppliers and physicians to purchase said pharmaceuticals from the manufacturers or distributors who had caused the Medicare and Medicaid programs to establish reimbursement rates enabling the supplier or physician to realize the greatest possible profit over and above the true cost of the pharmaceutical set by the manufacturer or distributor. (para 44)

At all times material to this civil action the DEFENDANT DRUG MANUFACTURERS were well aware that their false reports of AWP and AAC were causing the Medicare and Medicaid programs to establish grossly inflated reimbursement rates for the pharmaceuticals about which *the* DEFENDANT DRUG MANUFACTURERS provided false information. The DEFENDANT DRUG MANUFACTURERS perpetuated their fraudulent course of conduct for the express purpose of indirectly and directly maximizing their respective economic gains on the pharmaceuticals in question and with the knowledge that fraudulent conduct would cause the Medicare and Medicaid programs to expend federal moneys in the form of grossly excessive and unreasonable reimbursement. (para 45)

bar of § 3730(e)(4)(A). Instead, the investigation or report amounts to a jurisdiction-stripping public disclosure only if the investigation or report is in fact publicly disclosed." *United States ex rel. Wilson*, 528 F.3d at 307. *See also United States ex rel. Grayson v. Advanced Mgmt. Tech., Inc.*, 221 F.3d 580, 582 (4th Cir. 2000); *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1350 (4th Cir. 1994). Even more significantly, "[t]he mere fact … that the government is conducting an investigation behind the scenes, does not itself constitute public disclosure." *United States ex rel. Rost*, 507 F.3d at 728. In the absence of public disclosure, it makes no difference if the relator was itself aware of the government investigation, as VAC's testimony indicated. But the icing on the cake, jurisdictionally speaking, is that VAC was itself part of the instigation for this investigation and was working with the government to collect pricing information, as set forth above and in Exh. C, the Declaration of T. Mark Jones, and exhibits thereto.

Finally, Abbott makes a convoluted argument that the testimony of Bruce Vladeck, former HCFA Administrator, confirms that there was a prior public disclosure of Abbott's pricing. This is a rather amazing claim by Abbott, since Vladeck's testimony was about some (unidentified) articles in *Modern Healthcare* magazine from the 1980's and all Abbott could find – "after a manual search of a decade's worth of back issues," (Abbott Mem. at 16, n.7) – was one article from 1980 that talked about discounts offered to hospitals on IV solutions. *See* Esther Kuntz, *Hospitals Play Into Hands of Vendors Who Try to Break Group Contracts*, Modern Healthcare, July 1980 (cited in Abbott Mem. at 16). This article was 15 years old when VAC filed its action against Abbott, detailing then current reported and transaction prices for the subject drugs. The article addressed a totally different issue, as reflected by its title. Although some of the numbers apparently stuck in Mr. Vladeck's head, his 25-year-old memory as of the

time of his deposition in these cases merged retail and hospital prices. Most remarkably, no other "disclosure" was found in a decade's worth of issues.

It is indeed ironic that Abbott would contend that VAC was not an original source as to the AWP and kickback theories of fraud against it. VAC's earliest AWP-based disclosures to the federal (and State of Florida) governments pertained to Abbott and its drugs. Following a December 1994 meeting, VAC provided detailed Abbott pricing information to DOJ and OIG for Dextrose, Sodium Chloride, and Vancomycin – drugs presently at issue in the federal Abbott litigation. Some time in the first half of 1995, VAC provided information about a complaint to be filed against Abbott alleging AWP price inflation and improper inducement theories. The prices that VAC had available to it – and which were NOT otherwise available to the federal government – were prices initiated by Abbott, used in Abbott's direct contracts with VAC and marketed through the group purchasing organizations on Abbott's behalf to members such as VAC.

Ven-A-Care's spotting of Abbott's inflated prices, coupled with profit motives behind the ostensibly disconnected manufacturers,[27] and Ven-a-Care's painstaking and extended analysis of Abbott's pricing trends and patterns over time, sets it squarely within the realm of investigative relators that the courts have recognized as legitimate, valuable sources of information to the government. Abbott was one of the first companies whose fraud was apparent to VAC, through its analysis of price information that it obtained as an industry insider.

Abbott also contends that VAC cannot establish its original source status because the information that VAC provided to the government was not identified in discovery and therefore

[27] In virtually every AWP case, defendants argue that the alleged scheme makes no sense because they are not the recipients of the inflated reimbursement paid out by the government, and they are not even part of the transactions between the wholesalers and the pharmacies.

cannot be evaluated by Abbott or used by VAC. Relator's filings concurrent with this brief clearly set out the tremendous amount of Abbott specific information VAC provided to the government prior to filing its complaint. The vast majority of this information had previously been provided to Abbott in discovery, made available to it for use in the extensive Rule 30(b)(6) depositions of the relator, and specifically identified as materials presented to the government [Exh. C]. Clearly, Ven-A-Care has demonstrated to Abbott that it informed the government of Abbott's FCA violations before commencing its action.

E. Specific Arguments Relating to Dey

Like Abbott and Roxane, Dey trots out a litany of government GAO and OIG reports, apparently hoping that, with so many reports finding discrepancies between average prices and AWP, surely a few of them will count as "public disclosures." But, here again, not a single report that Dey points to names Dey or any of its NDC's at issue, and none of them even remotely suggests that such price discrepancies exist by reason of fraudulent conduct on the part of Dey.

Perhaps realizing this fatal flaw in its analysis, Dey focuses particular attention on four of these reports, one from February 1996 regarding nebulizer drug prices, two from June 1996 regarding Albuterol Sulfate unit dose prices and another from November 1998 that in part concerns prices for Ipratropium Bromide. Again, none of these reports names Dey, its NDC's, or even remotely suggests fraud. But Dey argues that these four reports nonetheless qualify as prior disclosures because, since Dey was one of only ten generic manufacturers of Albuterol unit dose and one of only three manufacturers of Ipratropium, Dey could be readily identified from these reports. Even if this were true, and a knowledgeable reader could identify Dey as one of

the manufacturers considered, such a reader would still be bereft of information suggesting that the price discrepancies addressed in the reports were created for a fraudulent purpose.

Even so, it stretches logic to suggest that a discerning reader could identify Dey as one of the manufacturers of the Albuterol products studied in the one nebulizer drug and two Albuterol reports, given that there were ten manufacturers of that product and no suggestion that all Albuterol manufacturers, let alone all nebulizer drug manufacturers, engaged in equivalent conduct. Furthermore, the report did not disclose that there were a limited number of manufacturers of that product. Meanwhile, the Ipratropium report not only postdates the addition of Dey as a defendant in Ven-A-Care's Second Amended Complaint in the Miami action, thereby disqualifying it as a prior public disclosure, but also fails even to address prices generally and currently paid in the marketplace for that drug. Instead, it focuses on prices at which the Veteran's Administration purchases such drugs, which prices are not implicated in any manner in Ven-A-Care's complaints. Prices available to the VA are vastly different than prices available in the retail pharmaceutical market. Therefore, even if Dey is identifiable in that report by reason of its (undisclosed) status as one of only three manufacturers of Ipratropium at that time, that report publicly disclosed nothing relevant to Ven-A-Care's complaints.

In the end, Dey abandons any pretense to identify a "public disclosure" within the statutorily enumerated forms of disclosure set forth in 31 U.S.C. § 3730(e)(4)(A). Instead, Dey posits that this Court should decline to find subject- matter jurisdiction over Ven-A-Care's cases-- not because of any such "public disclosures," but instead because anyone could have identified mega-spreads in the prices of Dey's products by simply comparing Dey's reported WACs or AMPs with its reported AWPs. However, this can form no part of a proper public disclosure analysis. AWPs and WACs are published in Red Book, Blue Book and First DataBank's

national drug price data file, and not in any news media or other publication set forth in the statute. Even if they were, the reported prices alone are clearly not enough to establish the fraud scheme as industry insider transaction prices are necessary in order to know that the reported prices are false. Dey apparently contends that its AMPs could have shown the falsity of its reported prices, but AMPs were held statutorily confidential and not publicly available from any source. Clearly, as Dey well knows, AMPs are not "public" information and cannot constitute a public disclosure of allegations or transactions on which VAC's complaint was based. Moreover, the discrepancies between Dey's WACs and AWPs provide no information suggesting that such prices were deliberately reported as part of a scheme that defrauded the federal Medicare and Medicaid programs and they certainly do not establish the actual ranges of prices generally and currently paid. Accordingly, these non-public disclosures disclose very little of the nature of Dey's true conduct.

Like Abbott and Roxane, Dey also suggests that Ven-A-Care cannot be an original source of any allegations in its complaints because it had no direct and independent knowledge of the transaction prices set forth therein. Dey Mem. at 11. It further suggests that Ven-A-Care is not an original source because, it asserts, Ven-A-Care based its allegations on government investigations. Id. at 16. Dey is incorrect on both counts.

First, the suggestion that Ven-A-Care did not have direct and independent knowledge of prices that Ven-A-Care learned of by virtue of its position as an industry insider has already been amply addressed in previous sections of this brief. Indeed, as earlier described, Ven-A-Care was a part of the very market towards which Dey's inducements were targeted. The fact that Ven-A-Care learned of the prices generally and currently paid for Dey's drugs through the vehicles and venues through which Dey typically propounded its prices to that marketplace is entirely

consistent with a determination of Ven-A-Care as an original source. Indeed, Dey marketed its actual transaction prices through avenues leading to industry insiders such as Ven-A-Care, and not the public. [Exh. E at 787:5-788:13, 815:20-816:6; Exh. C, Exh. 2 (VAC MDL 43585-43586)]. That Dey used such resources to market to industry insiders such as Ven-A-Care, in no way makes Ven-A-Care's information about Dey's marketing conduct and prices generally and currently paid in the marketplace any less direct or independent.

Apparently subscribing to the notion that evidence that it chose not to cite simply does not exist, Dey baldly asserts that "Ven-A-Care did not have a regular contact with Dey," but instead received all information secondhand. This is untrue, as evidenced by written communications from Dey to Ven-A-Care in 1996. By letter dated January 15, 1996, Dey sales representative Mari Carrell wrote, "I would like to thank you for taking the time to discuss Dey Laboratories." [Exh. BB (VAC MDL 53655), document marked "Attorney's Eyes Only" and Bates numbered R1-022880, marked as Exh. 525 at Mar. 3, 2003 deposition of Luis Cobo in *Texas v. Dey* case]. Seven months later, on August 22, 1996, Ms. Carrell faxed to VAC on Dey letterhead a price list for Dey's albuterol solution and inhaler, indicating on the fax cover sheet the AWP for each of those products, thereby providing VAC with an easy comparison of the prices at which Dey's products were generally and currently sold with the amount that Dey would deliberately cause to be reimbursed to Ven-A-Care by any third-party payors basing reimbursement in whole or in part on AWP. [Exh. CC (VAC MDL 53658), document marked "Attorney's Eyes Only" and Bates numbered R1-022883, marked as Exh. 530 at Mar. 3, 2003 deposition of Luis Cobo in *Texas v. Dey* case]. In just this manner was Ven-A-Care specifically targeted by Dey for inducement, created by Dey directly providing the transactional prices along with the inflated reported prices for Dey's albuterol products to Ven-A-Care.

Similarly, and equally without regard for the facts of record, Dey asserts that Ven-A-Care obtained the transactions and allegations upon which it bases its complaints from the very government investigations that Ven-A-Care prompted, participated in and provided with Dey's transactional prices. In this regard, Dey likens Ven-A-Care's acquisition of knowledge of Dey's fraudulent activities with respect to certain of Dey's drugs to that of the relator in *Seal 1 v. Seal A*, 255 F.3d 1154 (9th Cir. 2001), where the relator learned of fraud by a second company only through the government investigation of his allegations of the first company. Here, unlike the relator in *Seal 1*, VAC did not use the government investigations into its initial FCA action to discover evidence against entirely different defendants. To the contrary, as set forth earlier, VAC continued to assemble and assess its own insider information, providing a continuing stream to the government from which new allegations arose.[28]

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[28] Among many, many other instances as set forth in detail in Exh. C, with respect to Dey and its products, Ven-A-Care:

1. On March 19, 1996 sent a fax to Rob Vito, HHS OIG, regarding Albuterol, with Dey's prices attached. [Exh. C, Exh. 2, at VAC MDL 49888-49896].

2. On March 20, 1996 sent a fax to Mr. Vito regarding Albuterol. [Exh. C, Exh. 2, at VAC MDL 49881-49887].

3. On April 18, 1996 sent a fax to Mike Theis, DOJ, with advertisements regarding Albuterol and a statement regarding Ven-A-Care's intention to add Dey as a defendant in its FCA action. [Exh. C, Exh. 2, at VAC MDL 97552-97562].

4. On February 4, 1997 sent a fax to Mr. Vito regarding Dey Lab pricing for Ven-A-Care, and attaches Dey's contract pricing. [Exhibit EE (VAC MDL 49845-49848); Exh. C, Exh. 2 at VAC MDL 43554-43556].

5. On August 12, 1997 sent a letter to the U.S. Attorney for the Southern District of Florida and the U.S. Attorney General describing Dey's fraudulent practices with respect to Dey's Albuterol Sulfate solution and Cromolyn Sodium product, and enclosing its industry-insider information and documentation concerning same. *MPL 136.* For the specific documents provided to the government at this time, prior to the addition of Dey as a defendant in the Miami action, with respect to

There is no evidence to suggest that Ven-A-Care learned of any of the defendants' transaction prices or marketing conduct from the government. The record is dramatically replete with instances to the contrary, in which Ven-A-Care provided a steady stream of information to the government in order to instigate, prompt and assist with such investigations.

Even a government witness as actively and directly involved in the government investigations as David Tawes, Director of the HHS Office of Inspector General's Medicare and Medicaid Drug Pricing Unit, testified that Ven-A-Care provided OIG with prices for Ipratropium Bromide, and many other drugs, in or before 1997, and this information was used in the OIG's reports. [Exh. U at 704:2-17; 705:2-707:18]. In fact, Mr. Tawes unqualifiedly testified that the prices that Ven-A-Care provided to OIG for its reports consisted of confidential prices that were otherwise not accessible unless obtained through a company insider such as Ven-A-Care. [Exh. U at 872:1-16].

Dey's Albuterol, *see* Exh. FF (VAC MDL 73915) and Exh. GG (VAC MDL 71681), and with respect to Dey's Cromolyn Sodium, *see* Exh. GG.

6. On February 3, 1998 sent a fax to Mr. Vito regarding Dey's rebates on its drugs. Exh. C, Exh. 2 at VAC MDL 43454-43456.

7. On December 9, 1999 sent a letter to the U.S. Attorney for the Southern District of Florida and the U.S. Attorney General describing Dey's fraudulent practices with respect to Ipratropium Bromide, and enclosing its industry-insider information and documentation concerning same. Exh. MM (MPL 507).

8. On April 6, 2000 made a presentation to Suzanne Durrell, Assistant U.S. Attorney, and other personnel in the U.S. Attorney's Office for the District of Massachusetts regarding, among other things, Dey's fraudulent practices with respect to its Albuterol Metered-Dose Inhaler and Refill. [Exh. C, Exh. 2].

9. On April 7, 2000 sent a letter to the U.S. Attorney for the Southern District of Florida and the U.S. Attorney General describing Dey's fraudulent practices with respect to its Albuterol Metered-Dose Inhaler and Refill, and enclosing its industry-insider information and documentation concerning same. [Exh. II (VAC MDL 91359-91361)].

F. Specific Arguments Relating to Roxane

There was no public disclosure of Roxane's ipratropium bromide fraud before Ven-A-Care filed its complaint in this action, and Roxane has not identified any. As noted, *supra*, Ven-A-Care began providing pricing information to the government before and in 1997 [Exh. JJ (HHD013-1239); Exh. KK (VAC MDL 43715-43720)]. In arguing that there was public disclosure before VAC's complaint was filed, Roxane, like Dey, points to the 1998 OIG report which compares prices at which the Veterans Administration could purchase ipratropium bromide , plainly not a disclosure of allegations or transactions underlying the AWP price fraud since VA prices are not prices generally and currently paid by retail pharmacy providers. Roxane also points to a 1999 press release from Congressman Stark, Rox. Mem. at 9-10, which does not identify any company committing a fraud. A press release clearly is not the same as "news media" as defined by the FCA and even if it were, the press release in question was copied item by item from information provided to the Congressman by Ven-A-Care. (*Compare* Exh. C, Exh. 2 at VAC MDL 64215-64218 with Rox. Tab 130 Dkt. Nos. 6202 at Exh. 138 and 260 at Exh. 137). Ven-A-Care was indisputably an original source of this information.

Ven-A-Care's position as an industry insider for whom Roxane created the mega-spreads on its drug products provided it with direct and independent knowledge of the essential elements of the underlying fraud. [Exh. RR, Lockwood Tr., July 23, 2008, at 1076:4-1079:22]. Public reports, including the 2001 GAO report, did not identify mega-spreads or fraud, nor did they name Roxane or identify the size of or members of the relatively small group of manufacturers who produced ipratropium. There is no "public" notice of a specific manufacturer's fraud involving a specific drug when there are tens of thousands of NDCs and the government does not monitor specific drugs to determine how many companies manufacturer the drug at a given point

in time. Clearly, the FCA does not expect our government to devote scarce resources to follow such a moving target as companies enter and depart from competition with respect to a particular drug. Moreover, it is not what the government could have known, but what was publically disclosed that is important. *United States ex rel. Rost*, 507 F.3d at 728 ("The mere fact that the disclosures are contained in government files someplace, or even that the government is conducting an investigation behind the scenes, does not itself constitute public disclosure.")

VAC has been providing the government with information about drug price reporting fraud since 1993 [Exh. C]. Similarly, the original complaint in the Roxane action states that Medicare, some state Medicaid programs and defendants describe prices using AWP (¶ 27); state plans arrive at estimated acquisition costs using AWP (¶ 28); states use AWP in determining reimbursement (¶ 33); Roxane used financial inducements created by the spread between its true wholesale prices to pharmacies and state reimbursements based on falsely inflated wholesale prices (¶ 56); Roxane knew it was prohibited from making misleading price representations (¶ 66), and the acts by Roxane that caused the payment of false claims included "but were not necessarily limited to" making false representations about wholesale prices (¶ 86). [Exh. MM].

Ven-A-Care began tracking Roxane ipratropium bromide when it entered the market as the first generic in 1996 and VAC began to see the rapid inflation of the spread between 1997 and 1999 [Exh. G at 1143: 12-24; 1144:1-16]. Ven-A-Care timely provided its information about Roxane to the government. [Exh. C, Exh. 2 at VAC MDL 64633-64637; Exh. C, Exh. 2 at VAC MDL 64640-64646; Exh. JJ (HHD013-1239); Exh. KK]. Even if it could be found that there was any public disclosure of Roxane's ipratroprium false price reporting and AWP fraud before the filing of VAC's complaint, VAC had the requisite direct and independent knowledge to qualify as an original source and it properly informed the government of the fraud.

Roxane points to various state cases, including Ven-A-Care's Texas *qui tam* action, (Rox. Mem. at 11, Dkt. Nos. 6197 and 254), which disclosed the price reporting fraud allegations against Roxane before VAC amended its action to add numerous additional drugs. Roxane raises a distinction without a difference for FCA subject-matter jurisdiction purposes. As the United States Supreme Court noted in *Rockwell Int'l Corp. v. United States*, 549 US 457 (2007), amended pleadings will be reviewed on their own merit to determine if they allege a new or different action which must meet all requirements for subject matter jurisdiction. Ven-A-Care did not allege a new action as to Roxane, but merely added drugs that were part of the fraud scheme alleged in its original action and based upon the precise same theory of liability.[29]

The relator provided the government with the substance of a scheme by Roxane to defraud Medicare and Medicaid long before Roxane's fraud ever became public. As stated in *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 519 F. Supp. 2d 7, 13 (D. D.C. 2007), "It would make little sense to penalize the relator by restricting his ability to recover on additional claims of fraud arising out of the fraudulent scheme uncovered as a result of the relator's own diligent efforts."

Similarly, the Novaplus ipratropium information was not publically disclosed, *Chen Cheng Wang v. FMC Corp.*, 975 F.2d 1412, 1416 (9th Cir. 1992) and is no different than a new NDC for a drug previously identified by the relator, *see Miller*, *supra*; *see also Actavis*, 2009 U.S. Dist. LEXIS 92945 at *26.

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[29] There is no question that Ven-A-Care provided the United States with extensive disclosures of transaction prices about all of the Roxane products included in the 2005 amendment. Indeed, Roxane emphasizes the point that VAC provided the government with the Econolink database containing prices available in the market for all the additional drugs prior to 2001 – together with updates or "snapshots" from the Econolink database – well before those drugs were added in this action. (Roxane Defendants' Reply to U.S. Response to Roxane Defendants' Statement of Undisputed Material Facts ¶¶ 91, 93, 95; Dkt. No 01-12257 #6424; 06-11337 #404).

Roxane's arguments about disclosure of spread marketing are equally misplaced. Roxane totally ignores the allegation in ¶ 56 of the original April 10, 2000, complaint in this action, brought against only six defendants, that defendants were actively marketing "*their specified drugs* to pharmacies by use of financial inducements created by the 'SPREAD' between defendants true wholesale prices to the pharmacies and the State Medicaid Programs reimbursements …" based on defendants' falsely inflated prices reported to the state Medicaid programs (emphasis added). [Exh. MM]. One of the two Roxane drugs specified in that complaint was ipratropium. This allegation of spread marketing in 2000 plainly pre-dates the unsealing of each of the state complaints cited by Roxane at pages 11-14 it its brief. *See* Exhs. A-K of Roxane MTD, Dkt. Nos. 6197 and 254.

It does not matter that the data Ven-A-Care analyzed came from sources also available to others in the industry. Ven-A-Care used the Roxane AWPs as reported in Red Book and FDB together with information from invoices or from GPOs and wholesalers to calculate the spread over time, beginning in 1996 for Roxane Ipratropium Bromide and other Roxane drugs. [Exh. G at 1143:2-1144:16, 1255:10-1259:4]. VAC did not have the McKesson electronic database until 2000. [Exh. LL at 1081:10-20]. That database contained thousands of NDCs, was frequently updated and showed only a spread dollar, not percentage, difference. While it made the calculations easier, it did not diminish the need to look at rapidly changing prices for particular drugs over time in order to find and demonstrate the percentages of "megaspreads". Neither did it show, for example, the deliberate manipulation of prices such as Roxane's raising its reported AWP for furosemide while actual prices were dropping (*see* Roxane Response to US 56.1 SOF ¶¶ 84, 87 (01-12257 #6424; 06-11337 #404)).

Roxane argues that Ven-A-Care's claim that Roxane's WACs were inflated is based only on assumptions. The fraud alleged is not based on the exact price at which a wholesaler purchased from Roxane or on knowing the actual amount of the wholesaler markup. To the contrary, the WAC claims are based on information VAC received in the ordinary course of its business. It had transaction prices from wholesalers like ANDA which were materially below WACs reported in the compendia and could calculate the difference between these amounts and monitor it over time. [Exh. LL at 1131:8-22, 1132-1133:1-7, 1079:7-22, 1080:1-6].[30] Knowing that wholesalers were in business to make a profit, VAC could reasonably conclude that the true WAC was less then it was charged by a wholesaler in a non chargeback transaction. *Id.*[31]

Additionally, independent knowledge of marketing the spread does not depend on whether a salesman knocked on the door or knowledge of the process by which Roxane set its prices. The spread marketing consisted of the offering of prices to Ven-A-Care that were far lower than the AWPs reported by Roxane [Exh. G at 1233:22-1234:3; 1235:5-10; Exh. NN, Cobo Tr., Mar. 3, 2008, at 523:1 -524:11]. Ven-A-Care's independent knowledge came from the prices offered to it, the false reported prices and the resulting inflated spreads over time.

IV. CONCLUSION

The Relator respectfully submits that the Defendants have entirely failed to show that these actions were based upon a public disclosure as defined by 31 U.S.C. § 3730(e)(4) and, in any event, Relator has shown that it is an original source of the information upon which its

[30] *See, e.g.*, Original Complaint, ¶ 87.

[31] AMP's have nothing to do with this claim. The testimony contained in Roxane's Exhibit M, while outlining VAC's knowledge of market prices, related to specific allegations in ¶188 of the Complaint that Roxane's WACs and AMPs were, in some cases, 500% higher than its AMPs.

allegations are based. Accordingly, this Court possesses subject-matter jurisdiction over the Relator's False Claims Act cases and the Defendants' Motions should be denied in their entirety.

Dated: November 3, 2009

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2009, I caused a true and correct copy of the foregoing Plaintiff Ven-A-Care of the Florida Keys, Inc.'s Combined Opposition to Motions to Dismiss Filed by Abbott, Dey and Roxane to be served via LEXIS File & Serve electronic filing service pursuant to CMO #2 in this case.

/s/ Susan Thomas
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